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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,976	10/20/2003	Ileana Gabriela Sanchez De Rubio	491332000600	8662
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MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 300 MCLEAN, VA 22102				
			EXAMINER JOIKE, MICHELE K	
			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/687,976	Applicant(s) SANCHEZ DE RUBIO ET AL.	
	Examiner Michele K. Joike, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-9, 11-18, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 11-18, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed August 14, 2006. Claims 1-4 are amended. Claims 22 and 23 were added. Claims 5, 10 and 19-21 are canceled.

Claims 1-4, 6-9, 11-18, 22 and 23 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed February 14, 2006, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Priority

Applicant is reminded of the following in order to perfect priority. This application repeats a substantial portion of prior Application PCT/BR02/00057, filed April 19, 2002, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78. This relationship between the instant application and the parent application(s) must be recited, i.e. this application is a continuation-in-part of PCT/BR02/00057, filed April 19, 2002.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Brazil on April 19, 2001. It is noted, however, that applicant has not filed a certified copy of the Brazil application as required by 35 U.S.C. 119(b).

Drawings

The replacement drawing was received on August 14, 2006. This drawing is accepted.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 23 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 23 recites a method (process) without reciting any process steps that results in an improper definition of a process.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 9, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 depends from claim 3, which comprises vector pA-4. Therefore, the vector in claim 4 comprises two vectors, pA-4 and pGG7. It is unclear how a single vector can comprise two vectors.

Claim 22 recites the limitation "the 2.1 kbp EcoRI-EcoRI fragment" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 is unclear because it is a method claim but does not recite any method steps.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, -9, 11-18 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that vectors p1-9, p1-9g18, pA-4, and pGG are required to practice the invention. As such, the vectors must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the vectors. In the instant case, the process to generate the vectors that is disclosed in the specification does not appear to be repeatable, nor does it appear the vectors are readily available to the public.

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If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

a) during the pendency of the application, access to the invention will be afforded to the

Commissioner upon request;

b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;

d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

e) the deposit will be replaced if it should ever become inviable.

Response to Arguments Concerning Claim Rejections – 35 USC § 112(1)

Applicants' arguments filed August 14, 2006 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants argue that Figures 1 & 2 detail the construction schemes for producing the claimed vectors, and description of the vectors starts on page 3 of the specification. Together, they provide a repeatable method for producing the claimed vectors.

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Applicants' arguments have not been found persuasive for the following reasons.

Sufficient description has not been provided for the claimed vectors. The parent vectors are Ylp352ssh and YlpRH. These vectors are not well known in the art, and the genotype of these vectors is not provided in the specification, other than what is outlined in the drawings. Since these vectors are not readily available, the complete genotype is unknown, and there is no guidance in the specification on how to construct Ylp352ssh and YlpRH, it would be difficult to construct any vectors from them. Furthermore, since the complete gene sequences of p1-9, p1-9g18, pA-4 and pGG are not known, it is unclear how they would be obtainable by a repeatable method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 11, 12, 14, and 16-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al.

This rejection is maintained for the reasons set forth in the previous Office Action.

Response to Arguments Concerning Claim Rejections – 35 USC § 102(b)

Applicants' arguments filed August 14, 2006 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants argue that none of the references teach a yeast vector that is p1-9, p1-9g18, pA-4, pGG or functional variations, combinations or functional modifications thereof.

Applicants' arguments have not been found persuasive for the following reasons.

Applicants have stated on page 10 of their Remarks filed on August 14, 2006 that "functional" means that the claimed yeast vectors function by expressing nucleic acid sequences in yeast cells. Kobayashi et al teach a vector, pRDN-hyg 1, comprising 5S rDNA, NTS1, NTS2, *hyg 1* gene and *amp*. They also teach this vector transformed into a wild type yeast strain, with the transformant being stable for about 45 generations of growth. Interpreted broadly, the vector in the Kobayashi et al reference is a functional variation since it expresses a nucleic acid construct.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 13 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. in view of Fujiwara.

Claim 15 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. in view of Fincham.

Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. in view of Wai et al.

These rejections are maintained for the reasons set forth in the previous Office Action.

Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)

Applicants' arguments filed August 14, 2006 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants argue that none of the references teach a yeast vector that is p1-9, p1-9g18, pA-4, pGG or functional variations, combinations or functional modifications thereof.

Applicants have stated that "functional" means that the claimed yeast vectors functions by expressing nucleic acid sequences in yeast cells. Kobayashi et al teach a vector, pRDN-hyg 1, comprising 5S rDNA, NTS1, NTS2, *hyg 1* gene and *amp*. They also teach this vector transformed into a wild type yeast strain, with the transformant being stable for about 45 generations of growth. Interpreted broadly, the vector in the

Kobayashi et al reference is a functional variation since it expresses a nucleic acid construct.

Allowable Subject Matter

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.
Examiner
Art Unit 1636


DAVID GUZU
PRIMARY EXAMINER